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Pat Verduin, Ph.D.
Sr. Vice President and Director
Office of Product Quality and Development
Six ConAgra Drive - PDL 363
Omaha, NE 68102
Phone: 402/595-6560
Fax: 402/595-6559

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Office of Nutritional Products, Labeling
and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

RE: Carbohydrate Nutrient Content Claims Petition

ConAgra Foods, Inc submits this Citizen's Petition under Section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and Title 21, Section 101.69 of the Code of Federal Regulations, with respect to nutrient descriptor and labeling claims relating to the carbohydrate content of food. Currently, with no regulatory definitions or even policies in place, the marketplace is awash with direct and indirect "low carb" claims that are not based on a consistent level of carbohydrates in food and are confusing to consumers. Moreover, the proliferation of carb-lifestyle claims increases dramatically this clamor and confusion. ConAgra Foods respectfully requests that FDA establish definitions for four claims characterizing the carbohydrate content of both individual foods and meal type products: free, low, good source, and excellent source. ConAgra Foods also supports the current practice of defining "reduced" for nutrients, and applying that definition to carbohydrate claims. Finally, we are suggesting a way to minimize the confusion surrounding the indirect carb product and lifestyle claims. The

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definition of these terms is needed to facilitate consumer understanding of the range of carbohydrate content that may be consumed consistent with current dietary recommendations and to promote fair competition in the marketplace. All of the information specified as required in 21 CFR § 101.69 is included in this petition.

I. Statement of Proposed Descriptive Term

This petition seeks to extend availability to following existing nutrient content descriptors – “free”, “low”, “good source”, “excellent source” and “reduced or less” – to claims describing carbohydrates in individual foods and meal type products. The term “Meal type product” will include both meal products (as defined in 21 CFR § 101.13(l)) and main dish products (as defined in 21 CFR § 101.13(m)) in this petition. The general meaning of these terms is well established under the current regulatory framework and is as follows:

- Free – identifies the foods that contain a nutrient at inconsequential levels
- Low – identifies the foods that are distinctly low in a nutrient as compared to Daily Value (DV) and therefore can be eaten frequently without exceeding the dietary guidelines
- Good source – identifies a food that constitutes a significant contribution toward the DV for the nutrient
- Excellent source – identifies a food that contains exceptionally higher levels of a nutrient
- Reduced or Less – identifies nutritionally meaningful differences in nutrient contents

The use of the proposed terms would be subject to the general requirements specified in 21 CFR § 101.13.

II. Carbohydrate Background

Carbohydrates are a diverse group of macronutrients that may be divided into monosaccharides, disaccharides, oligosaccharides, polysaccharides and sugar alcohols. All fibers are non-digestible carbohydrates (IOM, DRI for Macronutrient, National Academy Press, September 2002). For labeling purposes, the “total carbohydrate” number on the Nutrition Facts Panel is “calculated by subtracting crude protein, total fat, moisture and ash from the total weight of the food” (21 CFR § 101.9(c)(6)). Included within that carbohydrate number are soluble and insoluble dietary fiber, sugars, sugar alcohols, and other carbohydrates. (*Ibid*). The primary function of carbohydrate is to supply energy to the cells in the body, especially the brain. All carbohydrates, except fiber, are broken down to simple carbohydrates by the digestive enzymes and absorbed through the small intestine. With the help of insulin, the carbohydrates are then taken-up by the cells for metabolic conversion into energy. The energy yield of digestible carbohydrate is 4 kcal per gram. Fibers are not digested and pass, relatively intact, into the large intestine. Some fibers are anaerobically fermented by the bacteria in the colon and produce short chain fatty acids (SCFA). These SCFA are then absorbed as an energy source. The energy yield from fiber is minimal and varies due to differences in food composition, patterns of food consumption, the amount of fiber, and metabolic status and the status of colonic microflora of an individual.

There has been a growing consumer interest in role of carbohydrates in human nutrition in the recent years. The interest has been fostered by scientific research, popular press, books and other anecdotal information related to its potential role in weight management.

III. Carbohydrate free

ConAgra Foods proposes that this term be defined as:

- a) For individual foods – less than 0.5 gram per labeled serving and per RACC.
- b) For meal type products (main dish and meal products) - less than 0.5 gram per labeled serving

Rationale: FDA has historically looked at the level of a nutrient that is reasonably classified as physiologically insignificant and at or near the reliable limit of detection, in defining the “free” claim and has therefore used the amount that may be declared as “0” in nutrition labeling as the basis for existing “free” claims. FDA has already established less than 0.5 gram per serving as equivalent to zero for purposes of nutrition labeling (21 CFR § 101.9(c)(6)).

IV. Low carbohydrate

ConAgra Foods proposes that this term be defined as:

- a) For individual foods – 6 g or less (2% Daily Value (DV)) per labeled serving and per RACC and not more than 50% calories from Carbs
- b) For meal type products (main dish and meal products) - 6 g or less (2% DV) per 100 g to a maximum of 20 g total per labeled serving and not more than 50% calories from Carbs

Rationale: (a) Individual foods: FDA has applied a flexible standard for defining a low amount of a nutrient, ranging from 2 percent of the DRV for nutrients that are highly distributed in food, to 4 percent for moderately distributed nutrients, to 6 percent for nutrients that are distributed at a low level in food (56 Fed. Reg. 60421, 60439-60440, November 21, 1991). Carbohydrates are highly distributed in foods. Foods products in over 50% (13 of the 23) food categories (USDA Nutrient Database, SR 16) are reasonably expected to contain carbohydrates

at significant levels (i.e. at-least 2% DV or 6 g). The remaining food categories where carbohydrate is not expected to be present at significant levels consist primarily of baby food, oils, meat, fish, poultry, spices and herbs. To account for the realistic eating patterns, foods in categories consist primarily of meat and fish products (6 categories) and are generally interchangeable in the diet. If baby foods are excluded and categories consisting of meat and fish products are counted as on, carbohydrates reasonably may be expected to be present in 13 of the 17 (over 76%) categories. Therefore, carbohydrates can reasonably be classified as being ubiquitous. The ubiquity of carbohydrate is also confirmed by the nutrient intake data from CSFII 1994-96, 1998. The median carbohydrate intake represented about 50%, in contrast intake of fat (FDA classifies fat as moderately distributed) to about 33% and protein about 15% of the total caloric intake.

The proposed definition of low carbohydrate is also consistent with the current dietary recommendations for carbohydrates as established by the IOM (IOM, DRI for Macronutrient, National Academy Press, September 2002). The report developed two important reference values for carbohydrate intake: an EAR (estimated average requirement) of 100 g per day for children over the age of one year and adults (excluding pregnant and lactating women) and an AMDR (Acceptable Macronutrient Distribution Range) of 45 to 60% of calories from carbohydrates. Assuming consumption of 16 to 20 servings of foods and beverages per day, person consuming all servings of low carbohydrate containing foods would consume 96 to 120 g carbohydrate per day and still meet the EAR recommendation. In the unlikely events when the EAR would not be met, de novo synthesis of glucose from dietary protein and/or fat would provide necessary glucose to meet the energy demands of the brain (IOM, DRI for Macronutrient, National Academy Press, September 2002).

The selection of 2% DV or less as the definition for low carbohydrate would also allow flexibility necessary for healthy carbohydrate consumption in a population with diverse macronutrient needs. This carbohydrate level would also provide a useful and meaningful reference point for carbohydrate conscious consumers to comply with meal patterns. The establishment of a 6 gram limit, for the "low" carbohydrate nutrient content claim criteria, challenges food processors/manufacturers to limit this claim primarily to foods that have undergone significant nutritional modifications, provide consumers with beneficial information, and to products with carbohydrate contents that are noticeably different than other foods not eligible to utilize this claim. ConAgra Foods recommends the additional requirement that 'not more than 50% calorie should come from carbohydrate', this would disqualify the foods that are traditionally considered as carbohydrate rich, especially those foods with very small serving sizes (RACC less than 30 g) from being eligible to use the claim.

(b) Meal type products: Since meal type products vary in serving sizes, to promote consistency, FDA has required a 'per 100 g' basis for "low" nutrient content claim for other nutrients (58 Fed. Reg. at 2379). ConAgra Foods recommends that the "low carbohydrate" claim criteria for meal type products (main dish and meal products) also be 'per 100 g' basis, due to the variable serving sizes, and to promote consistency with other nutrient content claim criteria for these products (21 CFR § 101.60 - 62). An additional requirement that "not more than 50% calorie can originate from carbohydrate" would disqualify a carbohydrate dense food from making the claim. ConAgra Foods proposes that a maximum carbohydrate content limit of 20 g per meal type product also be established, in order to maintain consumer confidence in the "low" claim for this product category. Without such a restriction the same large sized meal or entree could potentially be eligible for both a "low" and "good source" claim.

V. Good Source of Carbohydrate

ConAgra Foods proposes that this term be defined as:

- a) For individual foods – 15 g or more (5% DV) per labeled serving and per RACC
- b) For meal type products (main dish and meal products) - 30 g or more (10% DV) per labeled serving in the whole meal

Rationale: To emphasize the presence of a nutrient in food FDA has previously defined “Good Source” claims for foods containing 10 to 19 % of DV for eligible nutrients per RACC (21 CFR § 101.54). FDA has viewed the “Good Source” claim as characterizing a nutrient level that is significant from dietary point of view. In this regulation, FDA had excluded “total carbohydrate” (21 CFR § 101.54(a)) and reasoned that such a claim did not adequately distinguish between complex carbohydrate (recommended for increased consumption) and sugars (recommended for decreased consumption) (56 Fed Reg 60444, 58 Fed Reg 2345). Also, as there were no dietary recommendations existed for the complex carbohydrates, FDA did not provide any definition for “Good source of Complex Carbohydrate” (56 Fed Reg 60444, 58 Fed Reg 2345). IOM’s recent report “DRI for Macronutrient” (September 2002) established several quantitative recommendations: EAR of 100 g and an AMDR of 45 to 65% calorie from total digestible carbohydrate, and suggested a maximum intake of 25% of calories from sugar. These recommendations establish that digestible carbohydrates play a role in human nutrition, and provide a reasonable basis for defining the nutrient content claims “Good Source of Carbohydrate”.

(a) Individual Foods: ConAgra Foods recommends that the exclusion of carbohydrates be removed from 21 CFR § 101.54(a) and that a definition of a good source of carbohydrate be established. If a good source of carbohydrate were to be established at 10 to 19 percent of the

DRV of 300 grams, i.e., 30 to 59 grams, many food products that are traditionally regarded as rich in carbohydrate would be excluded, e.g., crackers, baked beans, ready-to-eat cereal, popcorn, pretzels, granola bars, and apple sauce. Accordingly, following prior FDA precedent (56 Fed. Reg. 60421, 60442-60443 (November 21, 1991); 58 Fed. Reg. 2302, 2344 (January 6, 1993)) ConAgra Foods recommends that FDA apply a factor of fifty percent, thus reducing the good source threshold level to 5% DV (15 g) of carbohydrate per RACC, in order to reach the “mid-level” range that FDA has established for this claim. This amount of carbohydrate also corresponds to 15% of 100 g EAR.

(b) Meal type products (main dish and meal products): ConAgra Foods recommends that the exclusion of carbohydrates be removed from 21 CFR § 101.54(a) and that a definition of a good source of carbohydrate be established at 10% DV or 30 g carbohydrate in the whole meal. This is consistent with the existing “good source” definition for the other nutrients (21 CFR § 101.54(c)). Meals have traditionally been treated differently than individual foods because of higher complexity and wide variability in serving size. Meals are more complex and carbohydrates in a meal can originate from multiple sources. Moreover, this value is significantly higher (50% more) than the proposed maximum amount for the proposed “Low Carbohydrate” claim.

VI. Excellent Source of Carbohydrate

ConAgra Foods proposes that this term be defined as:

- a) For individual foods – 30 g or more (10% DV) per labeled serving and per RACC
- b) For meal type products (main dish and meal products) - 45 g or more (15% DV) per labeled serving in the whole meal

Rationale: To emphasize the presence of a nutrient in food FDA has previously defined “Excellent Source” claims for foods containing over 20 % of DV for eligible nutrients per RACC (21 CFR § 101.54). FDA has viewed the “Excellent Source” claim as characterizing a nutrient level that is significant from dietary point of view. In this regulation, FDA had excluded “total carbohydrate” (21 CFR § 101.54(a)) and reasoned that such a claim did not adequately distinguish between complex carbohydrate (recommended for increased consumption) and sugars (recommended for decreased consumption) (56 Fed Reg 60444, 58 Fed Reg 2345). Also, as there were no dietary recommendations existed for the complex carbohydrates, FDA did not provide any definition for “Excellent source of Complex Carbohydrate” (56 Fed Reg 60444, 58 Fed Reg 2345). IOM’s recent report “DRI for Macronutrient” (September 2002) established several quantitative recommendations: EAR of 100 g and an AMDR of 45 to 65% calorie from total digestible carbohydrate, and suggested a maximum intake of 25% of calories from sugar. These recommendations establish that digestible carbohydrates play a role in human nutrition, and provide a reasonable basis for defining the nutrient content claims “Excellent Source of Carbohydrate”.

(a) Individual Foods: ConAgra Foods recommends that the exclusion of carbohydrates be removed from 21 CFR § 101.54(a) and that a definition of an excellent source of carbohydrate be established. If a good source of carbohydrate were to be established at over 20% percent of the DRV of 300 grams, i.e., over 60 g, many food products that are traditionally regarded as high in carbohydrate would be excluded, e.g., pasta, rice, orange juice, waffles. Accordingly, following prior FDA precedent (56 Fed. Reg. 60421, 60442-60443 (November 21, 1991); 58 Fed. Reg. 2302, 2344 (January 6, 1993)), ConAgra Foods recommends that FDA apply a factor of fifty percent, thus reducing the excellent source threshold level to 10% DV (30 g) of

carbohydrate per RACC, in order to reach the “mid-level” range that FDA has established for this claim. This amount of carbohydrate also corresponds approximately to 30% of 100 g EAR.

(b) Meal type products (main dish and meal products): ConAgra Foods recommends that the exclusion of carbohydrates be removed from 21 CFR § 101.54(a) and that a definition of an excellent source of carbohydrate be established at 15% DV or 45 g carbohydrate in the whole meal. If an excellent source of carbohydrate were to be established at over 20% percent of the DRV of 300 grams, i.e., over 60 g, most meal type products would be excluded. Accordingly, following prior FDA precedent (56 Fed. Reg. 60421, 60442-60443 (November 21, 1991); 58 Fed. Reg. 2302, 2344 (January 6, 1993)), ConAgra Foods recommends that FDA apply a factor of twenty five percent, thus reducing the excellent source threshold level to 15% DV (45 g) of carbohydrate per RACC, in order to reach the “mid-level” range that FDA has established for this claim. Meals have traditionally been treated differently than individual foods because of higher complexity and wide variability in serving size. Meals are more complex and carbohydrates in a meal can originate from multiple sources. This level would also provide significantly more carbohydrates (50% more) than good source.

VII. Comparative Carbohydrate Claims – Reduced and Less

ConAgra Foods supports the existing criteria (a 25% reduction) for “reduced” and “less” claims specifying (a) the reference foods that may be used to compare the level of nutrients, (b) information about the foods being compared and (c) the minimum amount of a nutrient by which food must differ (% reduction) in order to make the claim.

VIII. Disclosure Levels/”Healthy”

As noted above, carbohydrates are nutrients necessary for proper human functioning, and are required at fairly high levels for proper brain function. They are not, therefore, traditional

“nutrients of concern”, such as saturated fat or cholesterol. Moreover, depending upon the meal pattern, carbohydrates, especially fibers, can be “good for you” nutrients, which is the reason “good” and “excellent” source criteria have been suggested.

For these reasons, ConAgra Foods requests that FDA NOT include carbohydrates in the nutrients of concern required to be disclosed under 21 CFR § 101.13(h), nor included in the definition of “healthy”, a term FDA has stated is an implied nutrient content claim. For the reasons earlier described, a “healthy” level of carbohydrates is so individual; it would not be possible for FDA to establish a definition that is scientifically based for all persons.

IX. Basis for Proposed Terms

Consistent with section 403(a) of the FFDCA, the nutrient content claims proposed in this Petition are truthful and non-misleading. These claims are consistent with the latest dietary recommendations for carbohydrates. If approved, the proposed claims would extend the established nutrient descriptors “free”, “low”, “good source”, “excellent source” and “reduced or less” to carbohydrates. The existing general requirements governing the use of nutrient content claims would also apply to carbohydrate claims.

X. “Net Carbs” and Other Confusing Terms

Hundreds of food products on the market today have some sort of carbohydrate language on them. A few examples of labeling currently in the market place: “Carb Options”, “Carb Friendly”, “Carb Smart”, “Carb Conscious”, “Carb Sensitive”, “Carb Light” and “Carb Lite”, “Carb Control”, “Atkins Friendly” just to list a few. Exacerbating the consumer of confusion is the scientific sounding language “net carbs” and “effective carbs”, which are the carbohydrates remaining after subtracting from the total carb amount soluble and insoluble fiber, and in some cases sugar alcohols. With no regulations in place addressing these quasi-nutrient descriptor

claims, food companies are free to use their own definition and subtract out of the total carbs amount whatever carbs they choose in order to get to a low net carb amount for a claim on the Principal Display Panel. This kind of activity harms the public by misleading consumers into believing they will not gain weight eating a “low net carb” product, when in fact, scientific evidence may not support such a connection.

ConAgra Foods proposes that until FDA can get it’s arms around the current science and make a decision on what the definition of “net carbohydrates” means, a disclaimer and a rationale should be required on products (retail and foodservice) that use a “net carb” type claim.* That disclaimer would read “Not a low calorie food”, consistent with the “No sugar added” claim criteria. The “rationale” would need to contain the calculation used to arrive at the “net” number, and the rationale for the particular calculation used. The regulation could read: “When a claim is made regarding less than the total number of carbohydrates in a food, such as “net carbs”, anywhere on a food label or Point Of Purchase (POP) materials, except on the Nutrition Facts Panel (NFP), the claim must be accompanied by the calculation of the net number, and the rationale for the particular calculation used. In addition, if the food does not meet the definition of “low calorie” in 21 CFR § 101.60(b), then the disclaimer “Not a low calorie food” shall be prominently displayed in the same manner as described in 21 CFR § 101.60(c).”

Regarding the quasi-nutrient descriptor claims mentioned above, such as “carb conscious”, ConAgra Foods proposes that these claims on labels or POP materials must be accompanied by specific information informing the consumer of the meaning of the such terms,

* ConAgra Foods intends to submit supplemental materials and studies regarding “net carbs” in a separate submission.

and provide the amount of carbohydrates, total or net, in close conjunction with the quasi-nutrient descriptor claim.

XI. Nutritional Benefit to the Public

The proposed nutrient content claims would bring consistency to the marketplace where unauthorized claims are fostering consumer confusion. This would also increase consumer understanding of the role of carbohydrate in a healthy diet. FDA defined nutrient content claims would therefore benefit the public by addressing a demonstrated need for education.

XII. Conclusion

Due to the current level of consumer confusion and, indeed, misinformation in the marketplace, ConAgra Foods respectfully requests that FDA immediately undertake regulatory action regarding the following:

1. Define the four nutrient descriptor terms for carbohydrate set forth above: free, low, good source, excellent source claims;
2. Apply the existing criteria (a 25% reduction) for comparative claims to carbohydrates;
3. **NOT** incorporating carbohydrates into the disclosure levels described in 21 CFR § 101.13(h); and **NOT** adding carbohydrates to the “healthy” definition of 21 CFR § 101.65;
4. Establish a disclaimer for use of the word “net carbohydrate” or their synonyms anywhere on a food label (except the NFP) or in POP materials, indicating the product is “not a low calorie food”.

The table below summarizes the proposed claims:

Table 1: ConAgra Foods, Inc. Proposal – Carbohydrate Claims

Nutrient Claims	Individual Foods	Meals & Main Dish	Rationale
Free	< 0.5 g / labeled serving & RACC	< 0.5 g / labeled serving	Consistency with other nutrients
Low	≤ 6 g / labeled serving & RACC ≤ 50 % calorie from Carbs	≤ 6 g / 100 g ≤ 50 % calorie from Carbs Maximum 20 g / labeled serving	2% of DV A 16-20 serving/day, total carb consumption = 120 g/d vs EAR of 100 g/d Consumer perception of “Low”
Good Source	≥ 15 g / labeled serving & RACC	≥ 30 g from entire meal	Individual food – 5% DV Meal – 10% DV
Excellent Source	≥ 30 g / labeled serving & RACC	≥ 45 g from entire meal	Individual food – 10% DV Meal – 15% DV
Reduced	25% reduction labeled serving & RACC	25% reduction per 100 g	Consistency with other nutrients
Disclosure Levels	Not incorporate into disclosure levels, and not add to “healthy” definition	Not incorporate into disclosure levels, and not add to “healthy” definition	Carbohydrates can be “good for you” depending upon meal pattern
Disclaimer with “net carb” or synonyms	“not a low calorie food”	“not a low calorie food”	Consistent with “no sugar added” claim criteria

ConAgra Foods urges FDA to define Carbohydrate Nutrient Content Claims as soon as possible. ConAgra Foods is willing to provide any additional information as necessary.

Thank you.

Yours Sincerely,



Patricia Verduin, Ph.D.
Senior Vice President and Director
Office of Product Quality and Development